

REMARKS

Claims 1, 14-16, 19-21 and 27-48 will be pending in the above-identified application. Claims 2-13, 17 and 18 have been canceled herein without prejudice or disclaimer. Claims 1, 14, 19, 21, 29-32, and 34 have been amended to clarify the subject matter regarded as the invention. New claims 37-48 have been added. Applicant submits that the amendments and new claims are supported throughout the specification and, therefore, no new matter is added by these amendments and new claims.

Applicants gratefully acknowledge the Examiner's indication that claims 3 and 4 would be allowable if rewritten in independent form. Applicants point out that claim 1 has been amended and new claim 37 has been added, and claims 3 and 4 have been canceled. Current claims 1 and 37 incorporate each of the elements of allowable claims 3 and 4, respectively.

Rejections under 35 U.S.C. §103

Claims 1, 2, and 7-9 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (U.S. Patent No. 5,975,893, herein after referred to as "Chishti") in view of Wong *et al.* (U.S. Patent No. 6,206,695, herein after referred to as "Wong").

Although Applicant disagrees with the rejection and does not acquiesce to any reasoning stated by the Examiner, in order to further expedite the prosecution of the present case claims 1, 2 and 7-9 have been canceled herein without prejudice or disclaimer and while preserving Applicant's right to pursue claims of similar scope in a related later-filed, co-pending application. However, Applicants will address the rejection with respect to new claims 44-47.

Applicants respectfully disagree that Wong teaches using color as a non-numeric indicia to indicate order of use of dental appliances, as alleged in the Office action. For example, Applicants point out that while Wong discusses the well-known International Standard Organization (ISO) system that establishes industry manufacturing standards for endodontic instruments (i.e., endodontic reamers or files) used in performing a root canal operation, the ISO standardization system has nothing to do with prescribing order of use of dental appliances or any dental tool.

The ISO industry manufacturing standards (e.g., ISO Standard No. 3630) for the endodontic reamers defines factors such as shapes, profiles, lengths, sizes, acceptable manufacturing tolerances, and minimum requirements of mechanical stress, in order to ensure uniformity across the dental industry. Pursuant to ISO Standard No. 3630, the endodontic reamers are available in standard sizes defined by the diameter of the working tip, and the standard tip diameter of each reamer corresponds to the number used to identify it. However, the incrementally sized reamers are difficult to identify simply by looking at the tip diameters, and observation of small printed numbers is frequently obscured during an endodontic procedure by materials or the dentist's fingers (see, e.g., Wong at col. 3, lines 60-63). As such, ISO Standard No. 3630 also establishes a standard color scheme for the endodontic reamer handles, so that reamers with different tip diameters can more easily be distinguished. Thus, the ISO industry standard manufacturing color scheme is designed and used to more easily distinguishing differently sized endodontic reamers, and not in prescribing a specific order of use of the tools.

Moreover, Applicants point out that the mere fact that a dentist performing a root canal procedure, in general, may use progressively larger reamers does not provide the teaching of using a color scheme to designate a specific order of use of dental appliances. On the contrary, one of ordinary skill in the art would recognize that each reamer used at each step of a root canal procedure is selected at the discretion of the dentist and will be based on clinical factors such as age of the patient, disease progression, tooth structure, X-ray data, and the like. Nothing in the ISO industry manufacturing standards prescribes any particular order of use of the endodontic reamers in a root canal procedure.

Thus, Wong does not teach using color to indicate order of use, much less using color indicia comprising a dissolvable dye (e.g., as recited in claim 44) or using color indicia comprising a peel-away wrapper removably attached to an appliance (e.g., as recited in claim 47). The cited references fail to teach each and every element of the currently claimed invention, thereby precluding *prima facie* obviousness.

Accordingly, Applicants respectfully request that the rejection of claims 1, 2, and 7-9 under 35 U.S.C. §103(a) be withdrawn.

Claims 5 and 6 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (U.S. Patent No. 5,975,893) in view of Wong *et al.* (U.S. Patent No. 6,206,695) as applied to claim 2 above, and further in view of Rohlcke *et al.* (U.S. Patent No. 5,326,259).

Applicants initially point out that claims 5 and 6 have been canceled herein without prejudice or disclaimer. However, in order to be completely responsive to the Office action, the rejections will be addressed as they apply to the currently amended and new claims (see, e.g., claims 38 and 39).

The combination of Chishti and Wong is traversed for at least the reasons set forth above. Rohlcke fails to provide the teachings that are missing from Chishti and Wong. It is stated in the Office action that Rohlcke teaches "that a notch may be used as an alternative indicia" and that it would have been obvious to combine Rohlcke with the other cited references in order to make use of known alternative indicia. Applicants point out, however, that while Rohlcke may teach applying markings to metal orthodontic brackets to identify their orientation and allocation to specific individual teeth, nowhere does Rohlcke teach any markings for the designation of order of use. It is insufficient that the cited reference generically teaches "an indicia", the present claims require a non-numeric indicia designating an order in which each of at least some of a plurality are to be worn by a patient. Rohlcke fails to provide this teaching.

Thus, even if one of ordinary skill were to combine the cited references (even though no motivation has been identified to do so), the proposed combination would still fail to teach non-numeric indicia designating an order in which each of the at least some of the plurality are to be worn by a patient to provide dental treatment..., wherein the indicia comprises one or more cutouts so that each polymeric shell has a different cutout pattern. See, e.g., claim 38 and 39.

Accordingly, Applicants respectfully request that the rejection of claims 5 and 6 under 35 U.S.C. §103(a) be withdrawn.

Claims 10 and 11 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (U.S. Patent No. 5,975,893) in view of Wong *et al.* (U.S. Patent No. 6,206,695) as applied to claim 1 above, and further in view of Martin (U.S. Patent No. 6,884,071).

Claims 10 and 11 have been canceled herein without prejudice or disclaimer. However, in order to be completely responsive to the Office action, the rejections will be addressed as they apply to the currently amended and new claims (see, e.g., claims 40 and 41).

The Office action cites Martin at col. 7, lines 24-27 as teaching a bar code as an "alternative indicia". However, nowhere does Martin teach using bar codes for the designation of order of use. For example, reading further down from the citation made in the Office action, Martin states that "the coding can contain information about the mixing time, the material, the manufacturer and/or the expiration date" (see, Martin at col. 7, lines 28-29). Martin is silent as to using bar codes to indicate order of use. Martin fails to teach using non-numeric indicia designating an order in which each of at least some of a plurality are to be worn by a patient, as required by the current claims. See, e.g., claims 40 and 41.

Thus, even if one of ordinary skill were to combine the cited references (even though no motivation has been identified to do so), the proposed combination would still fail to teach non-numeric indicia designating an order in which each of the at least some of the plurality are to be worn by a patient to provide dental treatment..., wherein the indicia comprises a computer readable element. See, e.g., claims 40 and 41.

Accordingly, Applicants respectfully request that the rejection of claims 10 and 11 under 35 U.S.C. §103(a) be withdrawn.

Claims 12 and 13 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (U.S. Patent No. 5,975,893) in view of Wong *et al.* (U.S. Patent No. 6,206,695) and Martin (U.S. Patent No. 6,884,071), as applied to claim 10 above, and further in view of Morris *et al.* (U.S. Patent No. 5,923,001).

Claims 12 and 13 have been canceled herein without prejudice or disclaimer, however, the rejections will be addressed as they apply to the currently amended and new claims (see, e.g., claims 42 and 43).

The combination of Chishti, Wong, and Martin is traversed for at least the reasons set forth above. Applicants submit that Morris fails to provide the teachings that are missing from Chishti, Wong, and Martin. For example, while Morris teaches radio frequency identification tags, Morris fails to teach using such tags, or any other indicia, to identify order of use. Furthermore, the teachings of Morris focus on surgical sponges and blood loss during surgery, rather than the field of orthodontics. Thus, Morris appears to be non-analogous art.

Accordingly, Applicants respectfully request that the rejection of claims 12 and 13 under 35 U.S.C. §103(a) be withdrawn.

Claims 14-18 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti in view of Braverman (U.S. Patent No. 3,780,856, herein after referred to as "Braverman").

Although Applicants respectfully disagree with the rejections and do not acquiesce to any reasoning provided by the Examiner, claim 14 has been amended to clarify certain distinctions with the cited references and expedite prosecution. Claims 17 and 18 have been canceled without prejudice or disclaimer.

Applicants submit neither Chishti nor Braverman, alone or in combination, teach each and every element of the currently claimed invention. For example, neither references teach a plurality of packages comprising a non-numeric indicia on a package at an end of the chain indicating a dental appliance to be worn first, as required by current claim 14.

Accordingly, Applicants submit that even if, for arguments sake only, one of ordinary skill were to combine the cited references (even though no motivation has been established by the Examiner or is present in the references or elsewhere for making such a combination), the cited references would fail to teach each and every element of the claimed invention. As such, Applicants respectfully request that the rejections of claims 14-18 under 35 U.S.C. §103(a) be removed.

Claims 19-21 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti in view of Klein (U.S. Patent No. 4,038,753, herein after referred to as "Klein").

Although Applicants respectfully disagree with the rejections and do not acquiesce to any reasoning provided by the Examiner, claims 19 and 21 have been amended to clarify certain distinctions with the cited references and expedite prosecution. Claims 17 and 18 have been canceled without prejudice or disclaimer.

Applicants submit that neither Chishti nor Klein, alone or in combination, teach each and every element of the currently claimed invention. For example, Applicants point out that Klein, in fact, does not teach packaging "dental appliances" by providing them on a framework, as indicated in the Office action. Klein teaches tension-applying rings (e.g., elastic bands), rather than "dental appliances", disposed on a carrier. As taught by Klein, the tension-applying rings of the carrier are stretched, in no particular order, over hooks, brackets, etc of conventional orthodontic appliances (e.g., affixed "braces"). Thus, Klein does not teach dental appliances provided on a framework, as suggested in the Office action, and Klein certainly does not teach non-numeric indicia designating an order in which each of the plurality of dental appliances are to be worn by a patient to provide dental treatment, as required by current claim 19.

Therefore, even if, for arguments sake only, one of ordinary skill were to combine the cited references (even though no motivation has been cited by the Examiner or is present in the references or elsewhere for making such a combination), the cited references would fail to teach each and every element of the claimed invention. Accordingly, Applicants respectfully request that the rejections of claims 19-21 under 35 U.S.C. §103(a) be removed.

Claims 27-29 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti in view of Klatt (U.S. Pub. No. 2003/0136698, herein after referred to as "Klatt"). Applicants initially point out that claim 29 has been amended to depend from claim 28.

Applicants respectfully submit that the Examiner has failed to establish prima facie obviousness because no reasonable combination of the cited references would teach or suggest

the claimed invention. In particular, Applicants submit that the Examiner has failed to identify any suggestion or motivation, either in the cited references or the knowledge generally available to those of ordinary skill, to combine and modify the teachings of Chishti and Klatt so as to produce the claimed invention.

Nothing in Klatt teaches or suggests arranging dental appliances or placing them in any order of use. In fact, Klatt does not even deal with orthodontics, but instead teaches a medicinal product package for housing blister cards for microbe eradication therapy (e.g., antibiotic medication). Klatt does not teach or suggest using a blister card arrangement for anything other than microbe eradication therapy, and there appears to be no motivation or suggestion in the cited references for modifying the blister card arrangement of Klatt, or combine the teachings of Klatt with those of Chishti, to produce the claimed invention.

As is well known by the examiner, mere identification in cited reference of elements of the claimed invention is insufficient to defeat the patentability of a claim. To establish a prima facie case of obviousness based on a combination of elements disclosed in the cited references, the Examiner must articulate the basis on which it concludes that it would have been obvious to make the claimed invention. The Federal Circuit has recently stated that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness" (*In re Kahn*, 2006 WL 708687 (Fed.Cir.2006)). This precedent has been reinforced in myriad decisions. See, e.g., *In re Fritch*, 972 F.2d 1260, 1265 (Fed.Cir.1992) (the examiner can satisfy the burden of showing obviousness of the combination "only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references"); *In re Sang-Su Lee*, F.3d 1338 (Fed.Cir.2002); *In re Rouffet*, 149 F.3d 1350 (Fed.Cir.1998).

Applicants respectfully submit that, in the present case, no real reasoning has been articulated to support the Examiner's proposed combination and modification of the cited references. Instead, the Examiner merely offers the product of the combination (e.g., items in a package in their order of use) as the justification for making the combination in the first place.

Applicants further point out that although Klatt mentions order of use of the blister cards (e.g., Klatt, paragraph 0006), the stacking taught by Klatt indicate the number of days of medicinal treatment remaining in the eradication therapy. The blister cards of Klatt do not appear to be distinguishable from each other and, therefore appear to be more indicative of medicinal dose and daily amount, rather than particular order of particular blister cards.

Therefore, it is respectfully submitted that the rejections of claims 27 -29 under 35 U.S.C. §103(a) should be withdrawn for the reasons set forth above or, if the rejections are not withdrawn, that the Examiner provide some objective indicia, separate from the Applicant's own disclosure (e.g., impermissible hindsight), to support the Examiner's position that one of ordinary skill would have had any motivation to modify and combine the teachings of Chishti and Klatt and that such a modification would produce the claimed invention.

Claim 30 is rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti in view of Baggett (U.S. Patent No. 4,811,845, herein after referred to as "Baggett"). Applicants initially point out that claim 30 has been amended to clarify the appliances of the claim.

Applicants respectfully submit that no reasonable combination of the cited references would teach or suggest the claimed invention and, therefore, the Examiner has failed to establish prima facie obviousness. As above, Applicants submit that the Examiner has failed to identify any suggestion or motivation, either in the cited references or the knowledge generally available to those of ordinary skill, to combine and modify the teachings of Chishti and Baggett so as to produce the claimed invention.

Baggett teaches procedures for ensuring that a patient receives accurate doses of required medication at scheduled times. Baggett does not teach orthodontics or dental appliances or labeling packages housing a dental appliance with non-numeric indicia indicating order of usage. Baggett does not teach or suggest modifying the medication dosage procedures for a different field of use (e.g., orthodontics). As such, there appears to be no motivation or suggestion in the cited references for modifying the medication dosage procedures to produce the claimed invention.

Applicants respectfully submit that no suggestion or motivation is found in the cited references and no real reasoning has been articulated to support the Examiner's proposed combination and modification of the cited references. Therefore, it is respectfully submitted that the rejections of the claims be withdrawn or, if the rejections are not withdrawn, that the Examiner provide some objective indicia, separate from the Applicant's own disclosure (e.g. impermissible hindsight) to support the Examiner's position that one of ordinary skill would have had any motivation to modify and combine the teachings of Chishti and Baggett to produce the claimed invention. Accordingly, withdrawal of the rejection of claim 30 under 35 U.S.C. §103(a) is respectfully requested.

Claims 30 and 31 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chisti in view of Siedl (DE 3925088, herein after referred to as "Siedel").

Claims 30 and 31 have been amended to clarify certain distinctions with the cited references and expedite prosecution, although Applicants respectfully disagree with the rejections and do not acquiesce to any reasoning provided by the Examiner. Applicants submit neither Chishti nor Siedel, alone or in combination, teach each and every element of the currently claimed invention. In particular, while Siedel shows price labels with non-numeric strike-through marks, the marks do not indicate any order of usage.

Accordingly, Applicants submit that even if, for arguments sake only, one of ordinary skill were to combine the cited references (even though no motivation has been cited by the Examiner or is present in the references or elsewhere for making such a combination), the cited references would fail to teach each and every element of the claimed invention. As such, Applicants respectfully request that the rejections of claims 30 and 31 under 35 U.S.C. §103(a) be removed.

Claims 30, 32 and 33 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti in view of Fuller (U.S. Patent No. 1,508,095, herein after referred to as "Fuller").

Claims 30 and 32 have been amended to clarify certain distinctions with the cited references and expedite prosecution, although Applicants respectfully disagree with the rejections and do not acquiesce to any reasoning provided by the Examiner. Applicants submit neither Chishti nor Fuller, alone or in combination, teach each and every element of the currently claimed invention. While Fuller shows removal of numbers, the removal does not indicate any order of usage of anything.

Accordingly, Applicants submit that even if, for arguments sake only, one of ordinary skill were to combine the cited references (even though no motivation has been cited by the Examiner or is present in the references or elsewhere for making such a combination), the cited references would fail to teach each and every element of the claimed invention. As such, Applicants respectfully request that the rejections of claims 30 and 31 under 35 U.S.C. §103(a) be removed.

Claims 30 and 34-36 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti in view of Morrish *et al.* (U.S. Patent No. 4,726,970, herein after referred to as "Morrish").

Applicants initially point out that claims 30 and 34 have been amended to clarify certain distinctions with the cited references and expedite prosecution, although Applicants respectfully disagree with the rejections and do not acquiesce to any reasoning provided by the Examiner. Applicants submit neither Chishti nor Morrish, alone or in combination, teach each and every element of the currently claimed invention. While Morrish shows shaped indicia, the shaped indicia does not indicate any order of usage of anything.

Accordingly, Applicants submit that even if, for arguments sake only, one of ordinary skill were to combine the cited references (even though Morrish does not address anything in the orthodontic arts, and no motivation or suggestion for the proposed combination has been established by the Examiner), the cited references would fail to teach each and every element of the claimed invention. As such, Applicants respectfully request that the rejections of claims 30 and 34-36 under 35 U.S.C. §103(a) be removed.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

Date: _____

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